REMARKS

This amendment is responsive to the Office Action of September 8, 2008. Reconsideration and allowance of the claims 2-10 and 12-20 are requested.

The Office Action

Claims 1-4 and 6-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wesseler (US 5,534,228) in view of Tingey (US 2002/0168530).

Claim 5 stands rejected under 35 U.S.C. § 103 as being unpatentable over Wesseler as modified by Tingey, as further modified by Healy (US 5,425,435).

Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph.

The Present Amendment

The Examiner objected to the drawings regarding the mis-match in the numbers as recited on pages 6 and 7 versus the numbers shown in Figure 4. The applicant has addressed and corrected this problem by amending the numbering on pages 6 and 7 of the specification to match Figure 4. It is submitted that with this amendment, the drawings now comply fully with the Patent Office Rules and Requirements.

The specification has been amended to place it in more conventional US form and format.

Claim 10 has been placed in independent form, and many of the dependent claims have been amended to depend from it. Further, additional dependent and independent claims have been presented to focus more forcefully on the presently-presented concepts and to explore the avenues for patentability more completely. The new independent claims set forth the same combination of elements as original claim 1, but in many respects more limited.

Discussion

The present application addresses problems encountered with point of care testing (POCT). In point of care testing, a sample of a bodily fluid is taken from a patient, often blood drawn with a syringe. This sample is placed in a small container, e.g., a vial, which is configured to fit the point of care testing device.

Because the containers are small, it is sometimes difficult for the clinician to insert the needle of the syringe cleanly into the top closure. A first problem with which the present application is concerned is splashing. If the needle does not engage the closure cleanly, for example, the body fluid, e.g., blood, can be partially discharged exterior to the closure. This has several drawbacks. First, it is important to protect the clinician from blood-borne diseases. Second, the blood can coat all or part of the container. This not only creates a risk for others handling the container, but can also make the test results unreliable. Specifically, blood on the exterior of the container can contact and coat elements of the analyzer effectively carrying-over some of the blood to future samples, causing the future test results to lack reliability.

The present application addresses these issues in several ways. First, the closure is covered with Teflon which has several advantages. First, a droplet of blood on the Teflon surface will bead, rather than coating the surface, facilitating its easy removal and inhibiting contaminating the exterior surface of the container as might happen if the droplet of blood were to wet a portion of the closure or container. The Teflon also improves sealing to keep the blood from exiting the container. Further, a collecting space is provided into which the blood or other fluid can be injected by the syringe. This provides a buffer space which enables the POCT container to be filled more rapidly, expediting patient throughput.

Wesseler discloses a connector system for facilitating the transfer of liquid between IV bags or other containers. Wesseler includes a check valve 4 which enables a device connected with one end to be filled. Specifically, the breakoff piece 19 in Figure 4 is broken off and tubing from the supply container is connected to the tube 1. The breakoff piece 29 is broken off connecting piece 2 and tubing from the receiving container is connected to it. The connecting piece 2 is then snap fit into openings 38 and sealed by an O-ring 36. Fluid can now be transferred from the

supply container to the receiving container. After the fluids have been mixed in the receiving container, another connecting piece 6 is forced through the check valve 4, forcing it to remain open. After a breakoff piece 69 (Figure 6) is broken off, the fluid from the second container can flow through the second connecting device 2, the check valve 4, and the third connecting device 6. In this manner, Wesseler facilitates the transfer of fluids among fluid-receiving containers, but does not address the above-discussed problems encountered when filling POCT containers.

Tingey discloses a resilient closure that has a slit 21 through which a male Luer fitting 30 can be inserted. A top surface 13 of the resilient closure is coated with Teflon to reduce friction as the Luer fitting is received.

Tingey specifically teaches against coating the interior walls of the slit 21 as this might adversely affect the integrity of the seal (paragraph [0017]). It might be noted that there is a slight expanded space below the resilient seal element of Tingey, but this space is to receive the resilient element as illustrated in Figure 2 when the Luer connector is inserted.

The Claims Distinguish Patentably Over the References of Record

Claim 10 calls for a closure device that has a collecting space for receiving a fluid that can be introduced into the collecting space through the closure means. Neither Wesseler nor Tingey disclose such a fluid-receiving space. Each has a slightly enlarged area adjacent its resilient check valve. However, rather than being a fluid-receiving space, this space receives the check valve itself as it is flexed out of the fluid-conveying passage.

Accordingly, it is submitted that **claim 10 and claims 2-9 and 12 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 2 calls for a membrane or septum that is configured to be pierced by a needle tip through which the fluid is inserted into the collecting space and to seal itself when the needle tip is removed. Neither Wesseler nor Tingey disclose a septum or membrane which is configured to be pierced by a needle tip. By distinction, Tingey forces a resilient closure open by using a Luer fitting 30. Wesseler uses a similar tubular element 6 to force the check valve 4 open. Accordingly, it is

submitted that **claim 2 and claims 6, 7, and 9 dependent therefrom** distinguish yet more forcefully over the references of record.

Claim 3 calls for the closure means to be a membrane. Neither Tingey nor Wesseler disclose using a membrane as a closure means. Accordingly, it is submitted that **claim 3** distinguishes patentably over the references of record.

Claim 4 calls for the closure means to be a membrane or septum. Neither Wesseler nor Tingey disclose a membrane or septum used as closure means. Accordingly, it is submitted that **claim 4** distinguishes yet more forcefully over the references of record.

Claim 6 calls for the Teflon to be pierced by the needle tip. The Teflon layer 1 of Tingey serves as a low friction bearing surface for the Luer fitting 30, but is not configured to be pierced by a needle tip. Accordingly, it is submitted that **claim 6 and claims 7 and 9 dependent therefrom** distinguish yet more forcefully over the references of record.

Claim 8 calls for a needle guide that defines a funnel-shape opening to direct the needle tip towards the closure structure. Neither Wesseler nor Tingey disclose or fairly suggest a needle guide. Accordingly, it is submitted that **claim 8 and claim 12 dependent therefrom** distinguish patentably over the references of record.

Claim 9 calls for a Luer closure device which extends from the collecting space and which is configured to be attached to the opening of the container. In Tingey, the Luer fitting 30 is not a part of the closure device. Accordingly, it is submitted that **claim 9** distinguishes patentably over the references of record.

Claim 12 calls for a Teflon coating, this one applied to the funnel-shaped surface of the needle guide. Neither Wesseler nor Tingey disclose Teflon coated surfaces on a needle guide. Accordingly, it is submitted that **claim 12** distinguishes patentably and unobviously over the references of record.

Claim 13 calls for a collecting space and for a closure structure which is configured to be penetrated by a needle, among other limitations. Because neither of these limitations is disclosed or fairly suggested by Wesseler or Tingey, it is

submitted that **claim 13 and claim 14 dependent therefrom** distinguish patentably and unobviously over the references of record.

Claim 15 calls for a fluid collecting space and a closure structure which is configured to be penetrated by a tip of a needle. Neither Wesseler nor Tingey disclose either of these structures. Accordingly, it is submitted that **claim 15 and claims 16-20 dependent therefrom** distinguish patentably and unobviously over the references of record.

CONCLUSION

For the reasons set forth above, it is submitted that claims 2-10 and 12-20 are not anticipated by and distinguish patentably over the references of record. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is requested to telephone Thomas Kocovsky at (216) 363-9000.

Respectfully submitted,

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